

**Notice of Allowability**

Application No.

09/864,373

Examiner

Leon Y. Lum

Applicant(s)

KRISE ET AL.

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to May 24, 2006.
2. ☒ The allowed claim(s) is/are 8,9,10,11,12,17,18,19,20 renumbered as 2,3,4,5,1,6,7,8,9 respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with C. Joan Gilsdorf on July 27, 2006.

The application has been amended as follows:

I. Cancel claim 7.

II. For claim 8, delete "claim 7" and replace with -claim 12-.

III. For claim 9:

The apparatus of claim ~~7~~12 wherein the detector comprises ~~-further comprising an optical system with~~ a fiber optic lens and a bandpass filter.

IV. For claim 10, delete "claim 7" and replace with -claim 12-.

V. For claim 11, delete "claim 7" and replace with -claim 12-.

VI. For claim 12:

An apparatus for detecting a target molecule in a sample fluid in vivo or in vitro, comprising:

an uptake channel enclosed by a wall and having a receiving end to receive the sample fluid;

a matrix within the uptake channel, the matrix ~~being activated by binding~~ having a capture molecule for the target molecule to the matrix immobilized therein;

an inner tube connected to the matrix opposite the receiving end of the uptake channel;

a reservoir on a side of the matrix opposite the receiving end of the uptake channel, and formed by a wall extending from said wall of said uptake channel, said reservoir wall further extending beyond and surrounding said inner tube;

an analysis target area in said reservoir extending from an end of an the inner tube connected to opposite the matrix, the inner tube extending into the reservoir to form a bubble wherein a bubble from the sample fluid can be formed therein;

a reagent tag that binds to the target molecule and fluoresces when subjected to near-infrared near-infrared light emissions;

~~a pump assembly and a controller controlling the pump assembly to aspirate the sample fluid and the reagent tag into the uptake channel, through the matrix, and into the inner tube to form the bubble at the analysis target area;~~

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a light source focused directly on the analysis target area where the bubble is formed, ~~the light source configured to and emitting emit~~ light in a wavelength comprising near-infrared light emissions; and

a detector ~~configured to detecting detect~~ the reagent tag that fluoresces within the analysis target area when subjected to the light source.

VII. For claim 17, delete "claim 7" and replace with -claim 12-.

2. The following is an examiner's statement of reasons for allowance: the prior art discloses devices that provide fluid movement through a main channel for detection purposes at a specific matrix location within the channel. See for example, Zarling et al (US 5,674,698). However, the prior art fails to disclose an apparatus with a configuration requiring a reservoir wall extending from the wall of an uptake channel, the reservoir wall also extending beyond and enclosing an inner tube that is connected to the uptake channel, wherein a matrix with immobilized capture molecule therein is connected to the inner tube on one side and the uptake channel on another other side.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patent Examiner  
Art Unit 1641



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